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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,143	01/13/2002	Kenneth G. Mandel	C75101	8659

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GlaxoSmithKline
GLOBAL PATENTS -US, UW2220
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EXAMINER	
PALLAY, MICHAEL B	
ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
01/28/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/031,143	MANDEL ET AL.	
	Examiner	Art Unit	
	MICHAEL PALLAY	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response dated August 20, 2004, is acknowledged. Claims 1-12 are pending in the application.

The objection to abstract which was indicated in the previous Office action dated May 21, 2002, is withdrawn in view of applicant's remarks.

The claim rejection made under 35 U.S.C. § 112, second paragraph, which was indicated in the same Office action, is withdrawn in view of applicant's remarks.

The claim rejection made under 35 U.S.C. § 103(a) as being unpatentable over Phillips (U.S. Patent No. 5,840,737), which was indicated in the same Office action, is maintained for reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (U.S. Patent No. 5,840,737; filed July 15, 1996; issued November 24, 1998; of record).

Phillips discloses a method for treating gastric acid disorders including GERD (or heartburn) by administering to a human patient a pharmaceutical composition comprising an effective amount of omeprazole, a proton pump inhibitor, and sodium bicarbonate. See abstract, col. 1 lines 27-29, col. 12 line 38, and claims 1-3. Phillips also teaches that the amount of omeprazole to be administered with water is within the instant claims and one of the dosage forms is solid compressed capsule. See col. 12 lines 5-7 and lines 41-42, claim 12, and col. 1 line 25.

Phillips does not expressly disclose a method of treating or preventing heartburn symptoms particularly, in a human.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ Phillips' composition in a method of treating or preventing heartburn symptoms in a human, with a reasonable expectation of success.

One having ordinary skill in the art would have been motivated to employ Phillips' composition in a method of treating or preventing heartburn symptoms in a human since heartburn is well known to be one of the major symptoms of gastric acid disorders. Therefore, Phillips' composition would have been reasonably expected to benefit the treatment of heartburn in a human. Further, Phillips teaches that the composition is

expected to be useful in the treatment of heartburn as well as other gastric acid disorders.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed August 20, 2004, have been fully considered but they are not persuasive. Applicant argues that the prior Office action dated May 21, 2002, fails to establish a *prima facie* basis for obviousness under 35 USC 103 (page 4, paragraph 3). Specifically, applicant alleges that Phillips does not teach or suggest to one of ordinary skill in the art that a combination of an effective amount of proton pump inhibitor (PPI) and an effective acid-neutralizing amount of alkali metal bicarbonate salt would treat Gastroesophageal Reflux Disease (GERD) or heartburn. Applicant alleges that Phillips as a whole focuses on the prophylactic prevention of upper GI bleeding in critically ill patients, and that it is directed to reducing stress-related gastric mucosal damage rather than the relief of heartburn symptoms. See page 5, paragraph 1.

Applicant's arguments are not persuasive because Phillips does in fact teach the treatment of GERD (i.e., heartburn) using a combination of an effective amount of PPI and an effective acid-neutralizing amount of alkali metal bicarbonate salt, as noted in the prior Office Action. Phillips' abstract discloses, "A method for treating and/or preventing gastrointestinal conditions by administering to a patient a pharmaceutical composition including an aqueous solution/suspension of omeprazole or other

substituted benzimidazoles and derivatives thereof in a pharmaceutically acceptable carrier including a bicarbonate salt of a Group IA metal . . . ." Phillips mentions many gastrointestinal conditions, including GERD (i.e., heartburn) (column 1, lines 27-29). Phillips specifically notes, "The pharmaceutical composition including the omeprazole and derivatives thereof in a pharmaceutically acceptable carrier of a bicarbonate salt of Group IA metal can be used for the treatment of gastrointestinal conditions including, but not limited to, . . . GERD . . . ." (column 8, lines 47-52). As noted in the prior Office Action, Phillips teaches amounts or dosages that fall within the instant claimed amounts, and therefore are "effective amounts" (see column 12, lines 5-7, 41-42; examples; claims 4-12).

Applicant further argues that although Phillips discloses a known use of omeprazole for the short-term treatment of GERD, this disclosure is insufficient to suggest to a skilled artisan that a *specific selection* of a PPI-bicarbonate *combination* would provide rapid onset and prolonged relief of heartburn as disclosed by claim 1 of the present invention (page 5, paragraph 2). As noted above, Phillips does disclose the treatment of GERD (i.e., heartburn) using a combination of an effective amount of PPI and an effective acid-neutralizing amount of alkali metal bicarbonate salt. Regarding "rapid onset and prolonged relief," such is not mentioned in claim 1.

Applicant further argues that the cited sections of Phillips fail to support the use of an "effective amount" of proton inhibitor and "effective acid neutralizing" amount of alkali metal bicarbonate salt for the specific treatment of heartburn (page 5, paragraph 2). As noted above, Phillips does disclose the treatment of GERD (i.e., heartburn) using

a combination of an effective amount of PPI and an effective acid-neutralizing amount of alkali metal bicarbonate salt.

Finally, applicant argues that since Phillips fails to disclose or suggest an effective PPI-bicarbonate combination for heartburn treatment and is primarily directed to the treatment of upper GI bleeding, a skilled artisan, without more, would have little expectation of success in obtaining rapid-onset of heartburn symptoms using the methods described. As noted above, Phillips does disclose the treatment of GERD (i.e., heartburn) using a combination of an effective amount of PPI and an effective acid-neutralizing amount of alkali metal bicarbonate salt. Furthermore, although Phillips does discuss the treatment of upper GI bleeding, such teachings do not detract from another teaching of Phillips of the treatment of GERD (i.e., heartburn) using a combination of an effective amount of PPI and an effective acid-neutralizing amount of alkali metal bicarbonate salt. Regarding "rapid onset," such is not mentioned in the claims.

Response to Arguments

Applicant's arguments, see page 3, paragraphs 1-3, with respect to the abstract have been fully considered and are persuasive. The objection to the abstract is withdrawn.

Applicant's arguments, see page 3, paragraphs 4 and 5; page 4, paragraph 1, with respect to the use of the term "ANC" in claim 7, have been fully considered and are

persuasive. The rejection of claim 7 under 35 U.S.C. 112, second paragraph, is withdrawn.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL PALLAY whose telephone number is 571-270-3473. The examiner can normally be reached on Monday through Friday, 8:30 AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MBP

/GINA C. YU/
Primary Examiner, Art Unit 1617